AAM Statement for the Record
House Judiciary Subcommittee on the Courts, Intellectual Property, and the Internet
Hearing on "The Patent Trial and Appeal Board After 10 Years: Impact on Innovation and Small Businesses"
June 23, 2022

Thank you for holding a hearing on this important matter. AAM and its Biosimilars Council welcome the opportunity to submit this statement for the record and, in doing so, urges the Subcommittee to consider needed reforms to the Patent and Trial Appeal Board (PTAB) and inter partes review (IPR) process.

The PTAB and IPR are a critical check on the U.S. Patent and Trademark Office (PTO). On average, examiners at the PTO are given just nineteen hours to review patent applications.[1] This necessarily results in the granting of weak patents, some of which must be challenged in district court at great expense to the public and to the parties.

Abuse of the patent system can be costly for Americans, especially vulnerable patient populations who must take certain medications. For example, AbbVie filed over 240 patent applications for a single drug, Humira®, and received over 110 granted patents. These patents have allowed AbbVie to keep biosimilars off the market until 2023. And they present an insurmountable obstacle for potential biosimilar manufacturers—these manufacturers simply cannot take on that many patents, and companies like AbbVie know it. The effect of this trend is that litigation by generic and biosimilar drug developers to challenge some of these patents is often prohibitively expensive and risky.

IPR was designed to streamline and simplify this process, and it has indisputably worked. Indeed, many generic and biosimilar manufacturers have used IPR proceedings to successfully launch their alternatives, providing patients with earlier access to more affordable medications. For example, generic manufacturers successfully defeated the claims of a patent covering the drug Zytiga®, allowing for the launch of generic versions of the drug to treat prostate cancer.[2] Patients saved an average 81% on this life-saving medicine due to the availability of generic Zytiga®.[3] And through a series of IPRs, numerous other drug patents have been invalidated—in whole or in part—through IPR, including patents for Lantus®, Herceptin®, Rituxan®, Avastin®, and Neulasta®.[4]

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[1] Michael D. Frakes & Melissa F. Wasserman, Is the Time Allocated to Review Patent Applications Inducing Examiners to Grant Invalid Patents?: Evidence from Micro-Level Application Data, Nat'l Bureau of Econ. Research Working Paper 20337, at 7 (July 2014), http://www.nber.org/papers/w20337.pdf.
[2] *BTG Int'l Ltd. v. Amneal Pharm. LLC*, 923 F.3d 1063 (Fed. Cir. 2019) (affirming IPR decisions)
[3] *See* AAM, Let's strengthen IPR to accelerate patient access and lower prescription drug prices.
[4] *See* AAM, Statement for the Record, Senate Judiciary Committee Hearing on the "Support Technology and Research for Our Nation's Growth and Economic Resilience Patents Act of 2019 ('STRONGER')," at 2-3 (Sept. 11, 2019).

The PTO's examination process is not by itself sufficient to serve the public interest. Significantly, the examiner must accomplish a number of distinct tasks during the examination process and must do so within the 19-hour period. And the examiner's ability to search for prior art – much less to apply its teachings to the application – is highly constrained. That dearth of information is magnified by the PTO's "count" system, which is set up to reward productivity and not care.[5]

Congress passed the America Invents Act in 2012 creating the PTAB and IPR, which as noted has been successful in facilitating generic competition and contributing to lower prescription drug costs for patients. IPR allows the public to help identify patents that may have been granted in error and provides a process by which the PTO can take a second look at those patents. The PTAB system is faster and less expensive than the courts. It also uses subject matter experts within the PTO to maintain patent quality by reviewing the work of their patent examiners. This decreases the burden on the judicial system and market participants and provides benefits that are passed down to consumers and patients.

Litigation in federal district court is not an adequate forum by itself to weed out invalid patents. District court cases are slow-moving and costly. The parties generally litigate infringement as well as the invalidity of the patents. That means months or even years of fact and expert discovery. Significantly, the District of Delaware and the District of the New Jersey—two of the most popular forums for Hatch-Waxman litigation—have a median time to trial of 731 and 795 days, respectively.[6]

As a strong majority of the Supreme Court explained in upholding the Congress's work on the America Invents Act, IPR "protects 'the public's paramount interest in seeing that patent monopolies are kept within their legitimate scope.'"[7] The PTAB is far too important to patients and the developers of lower-cost medicines to diminish it. We encourage the Subcommittee to allow the PTAB to do the important work of taking a second look at questionable patents and, as a result, increasing competition in the pharmaceutical industry and lowering the cost of medicines for America's patients.

[5] Eric Blatt & Lian Huang, USPTO Incentive Policies Influence Patentability Decisions, available at https://www.law360.com/ articles/1052622/uspto-incentive-policies-influence-patentability-decisions.
[6] Pharmaceutical Patent Litigation Increases Nearly 30 Percent in 2017: Lex Machina Releases Fourth Hatch-Waxman/ANDA Litigation Report, available at https://lexmachina.com/media/press/lex-machina-releases-fourth-hatch-waxman-anda-litigation-report/.
[7] Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC, 138 S.Ct. 1365, 1374 (2018).